## THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

NYKJAER, et al.

Serial No.: 10/539,443

Filed: June 20, 2005

For: MODULATION OF ACTIVITY
OF NEUROTROPHINS

Confirmation No.:

## INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

## Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
- [] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).
- [X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).
- [] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).
  - [] i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.
- [] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- [] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).
- [ ] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).
  - 2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

- [] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.
- [X] A. Documents <u>AA-AE</u> are U.S. Patents or U.S. Patent Publications, and hence copies of these documents have not been provided. See 37 CFR 1.98(a)(2)(ii).
- [] B. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- [] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel <u>before</u> taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

a prior	application. A previously accepted PTO-1449, or an
examiner	-prepared PTO-892, necessarily complies with §1.98(b).
[X]	3. Document AF is not in the English language. In
accordan	ce with 1.98(a)(3), Applicants state:
[ ]	document already contain an English language
	abstract, summary or claim set.
[X]	a publicly available abstract is attached to document
	AF , and the source of each abstract is indicated
	thereon.
[ ]	documents are patents or published patent
	applications for which counterpart English language
	patents or patent applications exist, and are enclosed,
	as follows:
	Foreign Lang. Doc.# English Lang. Doc.#
	[insert] [insert]
[ ]	applicants have prepared an English translation of at
	least the pertinent portions of documents,
	and copies are attached.
[ ]	A concise explanation of the relevance of documents
	is found in the attached search report from
	the Patent Office (see reply to Comment 68 in
	the preamble to the final rules; 1135 OG 13 at 20).
[ ]	A concise explanation of the relevance of documents _
	appears in the present specification.

\_\_\_\_\_ is set forth as follows:
[Insert concise explanation of relevance]

[ ] A concise explanation of the relevance of documents

- 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- 5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

- 7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.
- 8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection

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with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.

Attorneys for Applicant

Зу:*\_\_<u>/</u>Х\_\_\_\_\_\_\_\_* 

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SHEET 1 OF 2

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE							RCE		ATTY DOCKET NO: NYKJAER=1			SERIAL NO: 10/539,443	
INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)						مرم	APPLICANT: NYKJAER, et al.						
Cose section should be harden by							0,	<u> </u>	FILING DATE: June 20, 2005			GROUP:	
U.S. PATENT	DOCUM	IENTS	(includ	de at le	altupa	tente	e, par	enthy	mber and issue	date)			
EXAMINER INITIAL		DOCUMENT NUMBER							DATE	PATENTEE	CLASS	SUB- CLASS	FILING DATE IF APPROP.
···	AA	6	6 3 0 0 3 2 7						October 9, 2001	Knusel et al.			
	AB	5	5	1	6	7	7	2	May 14, 1996	Glicksman et al.	-		
	AC	6	4	1	7	1	5	9	July 9, 2002	Riopelle et al.			
	AD	6	2	9	1	2	4	7	Sept.18,2001	Riopelle et al.			
	AE	20	01	00	64	6	9	5	November 29, 2001	Hadcock			
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)													
			D	OCUM	ENT N	IUMB	ER		DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
	AF	0	9	9	4	1	8	8	19 <sup>th</sup> April 2000	EP			YES
OTHER DOCL	JMENTS	inclu	de aut	hor, ti	tle, na	me o	f publi	cation	, volume, pages à	& date of publicatio	n)		
	AG K.E. Neet and R.B. Campenot. Receptor binding, internalization, and retrograde transport of neurotrophic factors. Cell. Mol. Life Sci. 58, 1021-1035 (2001)												
	АН		Lee et al. Regulation of cell survival by secreted proneurotrophins. Science 294, 1945-1948 (November 3, 2001)										
	Al	Moses Chao and Mark Bothwell. Neurotrophins: to cleave or not to cleave. Neuron 33, 9-12 (January 3, 2002)											
	AJ	Munck Petersen et al. Propeptide cleavage conditions sortilin/neurotensin receptor-3 for ligand binding. EMBO J. 18, 595-604 (1999)											
	AK	Hampe et al. The genes for the human VPS10 domain-containing receptors are large and contain many small exons. Human Genetics 108, 529-536 (2001)											
	AL												
	AM	Jacobsen et al. Molecular characterization of a novel human hybrid-type receptor that binds the α2-macroglobulin receptor-associated protein. J. Biol. Chem. 271, 31379-31383 (December 6, 1996)											
	AN												
	AO	Nielsen et al. The sortilin cytoplasmic tail conveys Golgi-endosome transport and binds the VHS domain of the GGA2 sorting protein. EMBO J. 20, 2180-2190 (2001)											
	АР	C. W		ann	and A					ctor: structure an		Cell. Mol. L	ife Sci. 58,
	AQ												
EXAMINER										DATE CONSIDER	ED		
	<b>EXAMINER:</b> Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form												
With next communication to applicant.													

		U.S. DEPARTMENT OF COMMERCE ADEMARK OFFICE	ATTY DOCKET NO: NYKJAER=1	SERIAL NO: 10/539,443					
LIST DO	CUMENT	SISCLOSURE STATEMENT  IS CITED BY APPLICANT  ets if necessary)	APPLICANT: NYKJAER, et al.						
			FILING DATE: June 20, 2005	GROUP:					
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)									
01/		Shirayama et al. Brain-derived neurotrophic factor produces antidepressant effects in behavioral models of depression. J. Neurosci. 22, 3251-3261 (April 15, 2002)							
DEC 01	AS PP	Lee et al. The uniqueness of being a neurotrophin receptor. Curr. Opin. Neurobiol. 11, 281-286 (2001)							
PAOEMAR	AT 44	Mazella et al. The 100-kDa neurotensin receptor is gp95/sortilin, a non-G-protein-coupled receptor. J. Biol. Chem. 273, 26273-26276 (October 9, 1998)							
	AU	Barbara L. Hempstead. The many faces of p75NTR, Curr Opin. Neurobiol, 2002 Jun; 12(3):260-7							
	AV	Jacobsen et al. Activation and functional characterization of the mosaic receptor SorLA/LR11. J. Biol. Chem. 276, 22788-22796 (June 22, 2001)							
	AW	Thoenen, "the changing scene of neurotrophic factors", Trends Neurosci. 14, 165-170 (1991)							
	AX	Raffioni et al., "THE RECEPTORS FOR NERVE GROWTH FACTOR AND OTHER NEUROTROPHINS" Ann. Rev. Biochem. 62, 823-850 (1991)							
	AY	Chao, "Neurotrophin Receptors: A Window into Neuronal Differentiation", Neuron 9, 583-593 (1992)							
	AZ	Appel, S. H., "A unifying hypothesis for the cause of amyotrophic lateral sclerosis, parkinsonism, and Alzheimer's disease," Ann. Neurol. 10, 499-505 (1981)							
	ВА	Duman et al., "A Molecular and Cellular Theory of Depression", Arch. Gen. Psychiatry 54, 597-606 (1997)							
	ВВ	Fahnestock et al., "The Precursor Pro-Nerve Growth Factor is the Predominant Form of Nerve Growth Factor in Brain and is Increased in Alzheimer's Disease", Mol. Cell. Neurosci. 18, 210-220 (2001)							
	BC	Nykjaer et al., "Sortilin is essential for proNGF-induced neuronal cell death", Nature Vol. 427, p843-848, 26 Feb 2004							
EXAMINE	ER		DATE CONSIDERED						
<b>EXAMINER:</b> Initial if reference considered. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.									